

REMARKS

According to the Office Action mailed March 29, 2005, Claims 1-52 are pending in the current application. Applicants have amended claim 19 to indicate that it depends upon claim 17 instead of claim 18. No new matter has been added.

The Examiner has required restriction to one of the following inventions:

- I. Claims 1-31, drawn to an immune modulation device (class 436, subclass 518);
- II. Claims 32-40, drawn to a method of modulating an immune system (class 435, subclass 4);
- III. Claim 41 and 42, drawn to a method of obtaining cells (class 435, subclass 7.1);
- IV. Claims 43-49, drawn to a method of manufacturing an immune modulation device (class 435, subclass 284.1); and
- V. Claims 50-52, drawn to an immune modulation device comprising pores formed by laser ablation (class 436, subclass 519).

Applicants hereby elect to restrict the application to the invention of Group I, claims 1-31. Claims 32-52, which are directed to non-elected inventions, have been withdrawn without prejudice to Applicants' ability to pursue these claims in other related patent applications.

Additionally, the Examiner has indicated that the claims are directed to patentably distinct species as well. Specifically, the Examiner has indicated that Claim 1 is generic and that patentably distinct species relate to:

Group A, drawn to a bioabsorbable immune devices is made from a polymer material selected from: aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylenes oxalates, polyamides, tyrosine derived polycarbonates, poly(iminocarbonates), polyorthoesters, polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes and biomolecules.

Group B, drawn to the aliphatic polyester selected from: homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide (including glycolic acid), ϵ -caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,4-dioxan-2-one), alkyl derivatives of trimethylene carbonate, delta-valerolactone, beta-butyrolactone, gamma-butyrolactone, ϵ -decalactone, hydroxybutyrate, hydroxyvalerate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-

dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2,5-dione, 2,5-diketomorpholine, pivalolactone, gamma, gamma-diethylpropiolactone, ethylene carbonate, ethylene oxalate, 3-methyl-1,4-dioxane-2,5-dione, 3,3-diethyl-1,4-dioxan-2,5-dione and 6,8-dioxabicyclooctane-7-one.

Group C, drawn to the shell material selected from: homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide including glycolic acid), ε-caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one, poly(p-dioxanone), glycolide-co-ε-caprolactone, glycolide-co-trimethylene carbonate, and glycolide-co-1,5-dioxepan-2-one.

Group D, drawn to a biocompatible fibrous scaffolding material selected from: homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide (including glycolic acid), ε-caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one, polyglycolide, poly(p-dioxanone), glycolide-co-ε-caprolactone, glycolide-co-trimethylene carbonate and glycolide-co-lactide.

Group E, drawn to a natural antigen selected from: *Actinobacillus equuli*, *Actinobacillus lignieresii*, *Actinobacillus seminis*, *Aerobacter aerogenes*, *Borrelia burgdorferi*, *Babesia microti*, *Klebsiella pneumoniae*, *Bacillus cereus*, *Bordetella pertussis*, *Brucella abortus*, *Brucella melitensis*, *Brucella ovis*, *Brucella suis*, *Brucella canis*, *Campylobacter fetus*, *Campylobacter fetus intestinalis*, *Chlamydia psittaci*, *Chlamydia trachomatis*, *Clostridium tetani*, *Corynebacterium acne* Types 1 and 2, *Corynebacterium diphtheriae*, *Corynebacterium equi*, *Corynebacterium pyogenes*, *Corynebacterium renale*, *Coxiella burnetii*, *Diplococcus pneumoniae*, *Escherichia coli*, *Ehrlichia phagocytophila*, *Ehrlichia equi*, *Fusobacterium necrophorum*, *Granuloma inguinale*, *Haemophilus influenzae*, *Haemophilus vaginalis*, Group b *Haemophilus ducreyi*, *Lymphopathia venereum*, *Leptospira pomona*, *Listeria monocytogenes*, *Microplasma hominis*, *Moraxella bovis*, *Mycobacterium tuberculosis*, *Mycobacterium laprae*, *Mycoplasma bovigenitalium*, *Neisseria gonorrhoea*, *Neisseria meningitidis*, *Pseudomonas maltophilia*, *Pasteurella multocida*, *Pasteurella haemolytica*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Rickettsia prowazekii*, *Rickettsia mooseri*, *Rickettsia rickettsii*, *Rickettsia tsutsugamushi*, *Rickettsia akari*, *Salmonella abortus ovis*, *Salmonella abortus equi*, *Salmonella dublin*, *Salmonella enteritidis*, *Salmonella heidelberg*, *Salmonella paratyphi*, *Salmonella typhimurium*, *Shigella dysenteriae*, *Staphylococcus aureus*, *Streptococcus coli*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Streptococcus mutans*, *Streptococcus Group B*, *Streptococcus bovis*, *Streptococcus dysgalactiae*, *Streptococcus equisimilis*, *Streptococcus uberis*, *Streptococcus viridans*, *Treponema pallidum*, *Vibrio*

cholerae, *Yersinia pesti*, *Yersinia enterocolitica*, *Aspergillus fumigatus*, *Blastomyces dermatitidis*, *Candida albicans*, *Cryptococcus neoformans*, *Coccidioides immitis*, *Histoplasma capsulatum*, influenza viruses, HIV, human papilloma virus, cytomegalovirus, polio virus, rabies virus, Equine herpes virus, Equine arteritis virus, IBR-IBP virus, BVD--MD virus, Herpes virus (humonis types 1 and 2), *Schistosoma*, *Plasmodium*, *Onchocerca*, and parasitic amoebas.

The Examiner alleges that the election of the species within Groups A-D is necessary given that each of the polymers has a different chemical structure. Applicants hereby make the following elections:

Group A: Applicants elect biomolecules as the species of polymer material used to make the bioabsorbable immune devices. Claim 18 reads thereon.

Group B: Applicants elect homopolymers and copolymers of glycolide as the species of aliphatic polyester. Claim 20 read thereon.

Group C: Applicants elect glycolide-co-ε-caprolactone as the species for the shell material. Claims 21 and 22 read thereon.

Group D: Applicants elect glycolide-co-lactide as the species of material for the biocompatible fibrous scaffolding. Claims 23 and 24 read thereon.

Additionally, the Examiner suggests that the antigens of Group E are patentably distinct because they have different biological functions and structures. Applicants respectfully traverse the Examiner's election requirement. The present immune device attempts to enhance the body's immune response by replicating the role of the lymph node. The humoral response to antigens, i.e. the role of lymph and lymph nodes in the generation of antibodies, is consistent irrespective of the biological function or structure of the microbe or virus presenting the antigen. Thus, contrary to the Examiner's assertion the species are not patentably distinct for purposes of the claimed device. Despite Applicants' traversal, in order to be completely responsive to the outstanding election requirement, Applicants elect influenza viruses as the natural antigen. Claim 31 reads thereon.

Entry of the foregoing remarks is respectfully requested. The fee of \$2,160.00 for a five month extension of time is enclosed herewith. No other fees are believed to be necessitated by the foregoing response.

Respectfully submitted,

Date: September 29, 2005

By: Fredrick J. Hamble 42,623
Fredrick J. Hamble (Reg. No.)

712 Kitchawan Road
Ossining, NY 10562
(914) 762-7586